PATENT Case No. 21288YP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Joseph L. Duffy, et a

Serial No.

10/537,476

Filed:

June 3, 2005

For:

PHENYLALANINE DERIVATIVES AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE TREATMENT OR

PREVENTION OF DIABETES

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Art Unit: To Be Assigned

Examiner:

To Be Assigend

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Deuse Brown

Date 8-25-2005

INFORMATION DISCLOSURE STATEMENT

5. Pursuance C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION			
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE		
10/530,215	April 4, 2005	21239YP		

	,		
If this is inconvenient, additional copies will b	e submitted upon request.		
6. In accordance with 37 C.F.R. 1.97, (ch	neck one)		
the attached information is filed within the	ee months of the filing dat	te of the captioned case.	
the attached information is filed more that Office Action on the merits.	in three months after the fi	iling date but prior to the m	ailing of a first
the attached information is being filed mo Office Action on the merits, but before th authorization is therefore given to charge	e mailing date of a Final A	ction or Notice of Allowanc	e. The enclosed
1.17(p). the undersigned certifies that each item cited in any communication from a foreig months prior to the filing of this Statemer	n patent office in a counte	this Information Disclosure rpart foreign application no	e Statement was first It more than three
the undersigned certifies that no item of i a communication from a foreign patent o person signing the certification after mak C.F.R. 1.56(c) more than three months p	ffice in a counterpart foreig ing reasonable inquiry, wa	gn application, and, to the l is known to any individual c	knowledge of the
		Respectfully submitted, By: Philippe L. Durette Attorney For Appl Reg. No. 35,125 MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-0907 (732)594-4568 Date: August 25, 2005	
		Date. August 25, 2005	

	Substitute for form 1449A/PTO				COMPLETE IF KNOWN
	INFORMATION I	DISC	CLOSURE	Application Number	10/537,476
	(1		Filing Date	June 3, 2005
	STATEMENT BY	9	LICANI	First Named Inventor	Joseph L. Duffy, et al.
	\ ```	٠,	,	Group Art Unit	
	(use as many sheets	igs ne	cessary)	Examiner Name	
Shee		of	4	Attorney Docket Number	21288YP

			U.S. PA	ATENT DOCUMENTS	
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	1	6,699,871 B2		Edmondson et al.	03/02/2004
·	2	6,011,155		Villhauer	01/04/2000
	3	6,166,063		Villhauer	12/26/2000
	4	5,939,560		Jenkins et al.	08/17/1999
	5	6,303,661 B1		Demuth et al.	10/16/2001
-	6	6,432,969 B1		Villhauer	08/13/2002
	7	4,386,090		Moinet et al	05/31/1983
	•	*** *** * * * * * * * * * * * * * * * *			

			<u> </u>		

	FOREIGN PATENT DOCUMENTS									
<u> </u>			Foreign Patent Document			Date of Publication of				
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY				
	8	PCT	WO 03/082817 A2		MERCK & CO., INC.	10/09/2003				
	9	PCT	WO 03/000180 A2		MERCK & CO., INC.	01/03/2003				
	10	PCT	WO 03/000181 A2		MERCK & CO., INC.	01/03/2003				
	11	PCT	WO 03/000181 A3		MERCK & CO., INC.	01/03/2003				
	12	PCT	WO 02/076450 A1		MERCK & CO., INC.	10/03/2002				
	13	PCT	WO 2004/007468 A1		MERCK & CO., INC.	01/22/2004				
	14	PCT	WO 2004/032836 A2		MERCK & CO., INC.	04/22/2004				
	15	PCT	WO 2004/050022 A2		MERCK & CO., INC.	06/17/2004				
	16	PCT	WO 2004/058266 A1		MERCK & CO., INC.	07/15/2004				
	17	PCT	WO 2004/064778 A2		MERCK & CO., INC.	08/05/2004				

Examiner Signature		Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

<u> </u>	Substitute for form 1449A/PTO				COMPLETE IF KNOWN
	INFORMATION I	DIS	CLOSURE	Application Number	10/537,476
	SZATEMENTAY	A TO	DI ICANIT	Filing Date	June 3, 2005
	/	AP	PLICANI	First Named Inventor	Joseph L. Duffy, et al.
	B AUG 2 9 2005 m			Group Art Unit	
	use as many skeets	as n	ecessary)	Examiner Name	
Shee	TA DEW	of	4	Attorney Docket Number	21288YP

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	U.S. Patent Docum Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
,								

			FOREIG	N PATENT	T DOCUMENTS	
_			Foreign Patent Document			Date of Publication of
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY
	18	PCT	WO 2004/069162 A2		MERCK & CO., INC.	08/19/2004
	19	PCT	WO 02/02560 A2		NOVO NORDISK A/S	01/10/2002
	20	PCT	WO 01/96295 A2		NOVARTIS AG	12/20/2001
	21	PCT	WO 01/96295 A3		NOVARTIS AG	12/20/2001
	22	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	23	PCT	WO 00/34241		NOVARTIS AG	06/15/2000
	24	PCT	WO 98/19998 A2		NOVARTIS AG	05/14/1998
	25	PCT	WO 98/19998 A3		NOVARTIS AG	05/14/1998
	26	PCT	WO 97/40832		Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
	27	PCT	WO 03/000180 A3		MERCK & CO., INC.	01/03/2003

Examiner Signature Date Considered

S	ubstitute for form 1449A/PTO				COMPLETE IF KNOWN
	INFORMATION I	DIS	CLOSURE	Application Number	10/537,476
	OIP	ATN		Filing Date	June 3, 2005
	TATEMENT BY	AP	PLICANI	First Named Inventor	Joseph L. Duffy, et al.
	2005		,	Group Art Unit	
	Abenant Speets	as ne	ecessary)	Examiner Name	
Sheet	3	of	4	Attorney Docket Number	21288YP

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
								
		·						

			FOREI	GN PATENT	DOCUMENTS	
, 	G:4-		Foreign Patent Documen	t	N CD	Date of Publication of
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY
	28	PCT	WO 02/02560	A3	NOVO NORDISK	01/10/2002
	29	PCT	WO 01/42262		AKZO NOBEL N.V.	06/14/2001
	30	PCT	WO 2004/043940		MERCK & CO., INC.	05/27/2004
	31	PCT	WO 2004/007468		MERCK & CO., INC.	01/22/2004
	32	PCT	WO 2004/110436		MERCK & CO., INC.	12/23/2004
	33	PCT	WO 2004/112701	A2	MERCK & CO., INC.	12/29/2004
	34	PCT	WO 2004/112701	A3	MERCK & CO., INC.	12/29/2004
	35	PCT	WO 2005/011581	A2	MERCK & CO., INC.	02/10/2005
	36	PCT	WO 2005/044195	A2	MERCK & CO., INC.	05/19/2005
	37	PCT	WO 2005/002530	A2	SMITHKLINE BEECHAM CORP.	01/09/2003

	· · · · · · · · · · · · · · · · · · ·		
Examiner Signature		Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

			The state of the s			
Substitute for form 1449R/PTO			COMPLETE IF KNOWN			
	DISC	CLOSURE	Application Number	10/537,476		
OIPE	A DD	T ICANT	Filing Date	June 3, 2005		
/	APP	LICANI	First Named Inventor	Joseph L. Duffy, et al.		
B AUG 2 9 2005			Group Art Unit			
(use as many stelets	as ne	cessary)	Examiner Name			
eet againgt	of	4	Attorney Docket Number	21288YP		
	STATEMENT BY AUG 2 9 2005 (use as many steets	STATEMENT BY APP AUG 2 9 2005 (use as many series as new	STATEMENT BY APPLICANT AUG 2 9 2005 (use as many selects as necessary)	SUBSTITUTE for form 1449BPPTO INFORMATION DISCLOSURE Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Decket Number		

NON PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.						
	38	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166, 2004.						
	39	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102, 2004.						
	40	K. Augustyns et al., "Dipeptidyl Peptidase IV Inhibitors as New Therapeutic Agents for the Treatment of Type 2 Diabetes", Expert Opin. Ther. Patents, Vol. 13(4), pp. 499-510, 2003.						
	41	Novartis AG: WO0034241, "Novel N-substituted-2-Cyanopyrrolidines as Potent Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Non-Insulin-Dependent Diabetes Mellitus", Exp. Opin. Ther. Patents, Vol. 10(12), pp. 1937-1942, 2000.						
	42	O. J. Orucker, "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes", Exp. Opin Invest. Drugs, Vol.12, 2004, pages 87-100.						
	43	T. P. Vahl & D. A. D'Alessio, "Gut peptides in the treatment of diabetes mellitus" Exp. Opin. Invest. Drugs, Vol. 13, 2004, pages 177-188.						
	44	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4128-4134.						
	45	Ann E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4135-4141.						
	46	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, 2004, pages 589-596.						
	47	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, Sept. 2004, pages 2181-2189.						

Examiner Signature	Date Considered	